IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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IN RE:	:	Master File No.:
PROPECIA (FINASTERIDE)	:	1:12-md-02331-JG-
PRODUCTS LIABILITY	:	VVP
LITIGATION	:	MDL No. 2331
This Document Relates To:	:	Honorable John Gleeson
	:	Magistrate Judge
ALL CASES	:	Viktor Pohorelsky

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DECEMBER 17, 2015

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Videotape deposition of ELIZABETH ROUND, M.D., taken pursuant to notice, was held at the law offices of Venable LLP, 1270 Avenue of the Americas, 24th Floor, New York, New York 10020, beginning at 9:06 a.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter and Notary Public in and for the State of New York.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

A. Uh-huh.
Q. Yes?
A. Yes.
Q. This document appeared in your custodial production, okay.
A. Okay.
Q. Referring to Exhibit-55, this is a peer-reviewed article from Traish, et al., entitled, "Adverse Side Effects of Five Alpha Reductase Inhibitor Therapy, Persistent Diminished Libido and Erectile Dysfunction and Depression in a Subset of Patients."
Do you see that there?
A. Yes.
Q. And it's got a date code of 2010 under -- right before the abstract.
Do you see that?
A. Yes.
Q. Why did you have this in your file?
A. Finasteride is a five alpha reductase inhibitor. PROPECIA® is a five alpha reductase inhibitor.

Q. So what?
A. The title says, Adverse Side Effects of Alpha Reductase Inhibitors.
Q. So were you evaluating -- were you reviewing this article to get an understanding of what the authors' conclusions were with respect to the impact of finasteride on persistent dysfunction of diminished libido and erectile dysfunction?
MR. MORROW: Objection.
THE WITNESS: It was a published paper about drugs that act as finasteride does, as a five alpha reductase inhibitor.
BY MR. BECKER:
Q. But it's a paper specifically on PROPECIA®, right?
MR. MORROW: Objection.
THE WITNESS: Five alpha reductase inhibitors. I believe it also includes dutasteride.
BY MR. BECKER:
Q. It included PROPECIA®,

right?

A. Correct.

Q. You read the paper?

A. Yes.

Q. What, if anything, did you do -- what did you do after you read it?

MR. MORROW: Objection.

BY MR. BECKER:

Q. What did you do with the information?

MR. MORROW: Same objection.

BY MR. BECKER:

Q. Did you do anything with the information after you read it?

MR. MORROW: Same.

THE WITNESS: We assimilated the information. We acknowledged that we had this information.

BY MR. BECKER:

Q. Do you know who Dr. Traish is?

A. Not personally. I know -- I mean, I just see him as the author here.

Q. I want to go through part of

this document with you.

Directing your attention to the results section. For the --

A. What page?

Q. The results on the abstract.

But before we do that, let me -- let me go back.

So you had a copy of this document in your file, correct?

A. Yes.

Q. And you read it, right?

A. Yes.

Q. And it's fair to say that the conclusion of this document is that Dr. Traish expressed some concern about persistent diminished libido and erectile dysfunction following discontinuation of use, correct?

A. Yes.

MR. MORROW: Objection.

Document speaks for itself.

BY MR. BECKER:

Q. And after reviewing this document, is it fair to say that Merck

took no action?

MR. MORROW: Objection.

BY MR. BECKER:

Q. To change the label?

MR. MORROW: Same.

THE WITNESS: There was no change to the label.

BY MR. BECKER:

Q. Okay. Let's go through the document. In the results section of the abstract, it says, Prolonged adverse effects on sexual dysfunction such as erectile dysfunction and diminished libido are reported by a subset of men, raising the possibility of a causal relationship.

Did I read that correctly?

A. Yes.

Q. What's your opinion on that?

MR. MORROW: Objection.

BY MR. BECKER:

Q. Well, you were -- or are a clinician, clinical researcher at Merck for the better part of the last quarter

century, right?

A. Right.

Q. Your job, part in part, is to identify causal risks associated with known drugs, right?

MR. MORROW: Objection.

BY MR. BECKER:

Q. Right?

A. Yes.

Q. Okay. So what I'm asking you is, did this give you any concern, Dr. Traish's report, that there may, in fact, be a causal relationship between finasteride and persistent ongoing sexual dysfunction?

MR. MORROW: Objection.

THE WITNESS: He raised the possibility, the possibility of a causal relationship.

BY MR. BECKER:

Q. I'm sorry, I didn't mean to interrupt you.

A. No. I mean, he didn't really have a lot of objective evidence

in this paper.

Q. So he raised the possibility of a causal relationship, right?

A. Yes.

Q. And armed with that knowledge, Merck did nothing to change the label, true?

MR. MORROW: Object to the form.

THE WITNESS: We did not change the label based on this paper.

BY MR. BECKER:

Q. Turn to the next page of the document, if you would.

Do you see in the second column?

A. Yes.

Q. The paragraph that starts with, The potential widespread.

A. Uh-huh.

Q. Okay. About six sentences down, Dr. Traish writes, To date.

Do you see that?

A. Yes.

Q. To date the adverse side effects of five alpha reductase inhibitors on sexual function, gynecomastia and the impact on the overall health have received minimal attention. However, in some patients, these side effects are persistent with regard to sexual function and with emotional toll, including decreased quality of life.

Did I read that correctly?

A. Yes.

Q. Do you agree or disagree with that statement?

MR. MORROW: Objection.

THE WITNESS: I don't have a basis to agree or disagree with that statement.

BY MR. BECKER:

Q. Well, didn't you testify earlier that your job was to figure out causal relationships of identified risks associated with the pharmaceutical?

MR. MORROW: Object to the form.

THE WITNESS: Yes.

BY MR. BECKER:

Q. And one of the risks associated with the use of PROPECIA® that Dr. Traish is raising is persistence with regard to sexual -- decreased sexual function and emotional issues, right?

MR. MORROW: Object to the form.

BY MR. BECKER:

Q. That's one of the things he's talking about; isn't that true?

MR. MORROW: Same objection.

THE WITNESS: That's one of the things he's talking about.

BY MR. BECKER:

Q. So I'm asking, as a clinician who has worked at Merck for the better part of 25 years, do you agree or disagree with that statement?

MR. MORROW: Same objection. Asked and answered.

THE WITNESS: He's making an introductory statement here.

BY MR. BECKER:

Q. That doesn't answer my question, ma'am.

A. He's not --

MR. MORROW: Let her finish her answer.

BY MR. BECKER:

Q. My question is a yes-or-no question. It's you either agree or disagree with the statement, Doctor?

MR. MORROW: That's not necessarily true. Objection.

THE WITNESS: He makes the statement: However, in some patients these side effects are persistent.

BY MR. BECKER:

Q. That's right. And I'm asking whether or not you agree with that.

MR. MORROW: Objection.

THE WITNESS: I don't know

that he's proved to me they're persistent.

BY MR. BECKER:

Q. So you do not agree to with, then?

MR. MORROW: Object to the form.

THE WITNESS: I said he has not proved to me these are persistent.

BY MR. BECKER:

Q. Let me see if I can do it this way.

If he hasn't proved it to you, are you taking the position that you don't believe him?

MR. MORROW: Objection.

THE WITNESS: I believe that some of this data is very flawed.

BY MR. BECKER:

Q. That's not my question, Doctor. My question is simply, do you believe the statement that these effects, sexual dysfunction, are persistent with

regard to some patients? Do you believe that?

MR. MORROW: Object to the form. Asked and answered.

BY MR. BECKER:

Q. Do you believe that some men who take finasteride will, in fact, have ongoing sexual dysfunction following discontinuation of use?

MR. MORROW: Object to the form.

THE WITNESS: I do not know that that has been definitively proved.

BY MR. BECKER:

Q. That wasn't my question.

My question was, do you believe it's possible?

MR. MORROW: Objection. Speculation. She answered your question. You just don't like the answer.

THE WITNESS: I believe men can get persistent sexual

dysfunction, whether it's related to finasteride therapy or not, I don't know.

BY MR. BECKER:

Q. Now, we looked at an e-mail earlier, right, where you had evidence of a man who had persistent sexual dysfunction following discontinuation of use, right?

MR. MORROW: Objection.

THE WITNESS: I had evidence of a man whose sexual AE was still present 66 days after he finished therapy.

BY MR. BECKER:

Q. Does 66 days fit into your definition of --

A. I don't have a definition.

Q. Turn to Page 4 of document.

Do you see this highlighted section here, Doctor? Dr. Traish writes, Additional evidence is found in clinical studies and in the Merck database, which strongly suggest that in some patients

these sexual adverse effects are persistent.

Did I read that correctly?

A. Yes.

Q. Do you agree with that statement?

MR. MORROW: Objection.

THE WITNESS: I have no idea what he's referring to there.

BY MR. BECKER:

Q. We looked at a document that had -- we looked at the document regarding the Phase 3 clinical trials that reported, from the trials --

A. Yes.

Q. -- persistent ongoing sexual dysfunction, correct?

MR. MORROW: Objection.

THE WITNESS: I'm not sure how -- where he's making this statement from. Additional evidence is found in the clinical studies and in the Merck database.

MR. BECKER: I'm going to --

I have to object to that.

THE WITNESS: All right.

BY MR. BECKER:

Q. Doctor, I need you to listen to the question that I'm answering -- I'm asking and answer those.

A. Okay.

Q. Okay. If your lawyer wants to ask you questions at the end, he's free to do that.

A. Okay.

Q. But I need you to answer my questions.

A. Okay.

Q. And my question is this: We looked at a document that was an e-mail to you and Dr. Kaufman that said, or evidenced, persistent ongoing sexual dysfunction from the Phase 3 clinical trials, right?

MR. MORROW: Objection.

THE WITNESS: From years three to five, yes.

BY MR. BECKER:

Q. And you testified earlier that Sweden amended the label in 2009 to reflect persistent ongoing sexual dysfunction, correct?

MR. MORROW: Objection.

THE WITNESS: Yes.

BY MR. BECKER:

Q. And that information was corroborated by Merck's adverse event database and reports of ongoing sexual dysfunction in that database, right?

MR. MORROW: Objection.

THE WITNESS: Yes.

BY MR. BECKER:

Q. And that information was reported publicly, correct?

A. Yes.

Q. Isn't that what he's talking about here, that there was evidence from the Merck database, that's the adverse event database, suggesting persistent ongoing sexual dysfunction?

MR. MORROW: Object to the form.

THE WITNESS: That's why I asked the question, I didn't know what he was referring to.

BY MR. BECKER:

Q. Well, you have an understanding, Doctor, as a 25-year employee of Merck, that there is an adverse event database, right?

A. Correct.

MR. MORROW: Objection.

BY MR. BECKER:

Q. And that adverse event database is put in place so that Merck and regulatory agencies can identify signals of potential causative risks associated with the use of a drug, right?

MR. MORROW: Objection.

THE WITNESS: It's put in place to collect adverse events in postmarketing.

BY MR. BECKER:

Q. So as to identify potential causative risks of the use of a drug, right?

MR. MORROW: Objection.
THE WITNESS: Yes.
BY MR. BECKER:
Q. That was a yes, right?
MR. MORROW: Objection.
THE WITNESS: Yes.
BY MR. BECKER:
Q. And upon reviewing that information, Sweden required you to change the label to reflect persistent erectile dysfunction following discontinuation of use?
A. Yes.
Q. Okay. So my question is, do you agree or disagree that additional evidence is found in the clinical studies and in the Merck database which strongly suggests that in some patients the sexual adverse effects are persistent?
MR. MORROW: Objection.
THE WITNESS: I'm not -- I'm not clear what studies he's referring to when he says "in clinical studies;" what studies he

has access to, what he's talking about.

BY MR. BECKER:

Q. I'm simply asking, Doctor, whether you agree or disagree with this statement? You either do or you don't.

MR. MORROW: Object to the form.

THE WITNESS: I'm not sure that it's strong evidence.

BY MR. BECKER:

Q. How about some evidence?

MR. MORROW: Objection.

BY MR. BECKER:

Q. The fact of the matter is, Doctor, there is evidence in your database, in Merck's database and in the Phase 3 year three through five clinical trials that suggests that some -- that in some patients, the sexual adverse effects are persistent; isn't that true?

MR. MORROW: Objection.

THE WITNESS: There are reports of persistent sexual

adverse events in the Merck database.

BY MR. BECKER:

Q. So is that a yes, that is true?

MR. MORROW: Objection.

THE WITNESS: That -- that is true. I would not put it in this context. You're asking me to agree with the whole sentence.

BY MR. BECKER:

Q. He goes on to say, Clearly the sexual adverse events do not necessarily resolve completely in all patients who discontinue use of finasteride, again supporting the premises that in some patients, these sexual side effects remain persistent.

Did I read that correctly?

A. Yes.

Q. Do you agree or disagree with that statement, Doctor?

MR. MORROW: Objection.

THE WITNESS: He's talking

about in the postmarketing reports, yes.

BY MR. BECKER:

Q. So you agree --

A. In the postmarketing reports.

Q. Let me finish my question, Doctor.

You agree that -- that sexual adverse events do not necessarily resolve completely in all patients who discontinue use of finasteride?

MR. MORROW: Object to the form.

THE WITNESS: Based on the postmarketing reports. He introduces that section by talking about postmarketing.

BY MR. BECKER:

Q. You agree with that statement? That's all I'm asking.

MR. MORROW: Objection.

THE WITNESS: That's the AEs that are in the label now.

BY MR. BECKER:

Q. Well, but, Doctor, in fairness, the AEs that are in the label are buffered by the sentence that they discontinue upon -- that they go away -- they resolve upon discontinuation, right?

MR. MORROW: Object to the form.

THE WITNESS: I was referring to the postmarketing section.

BY MR. BECKER:

Q. Well, but this is prior to the amendment to the U.S. label, right?

A. What is? This paper?

Q. This article is written in 2010, is it not?

A. Yes.

Q. Okay. And you had yet to -- Merck had yet to amend the United States label to reflect the fact that postmarketing surveillance reported persistent ongoing sexual dysfunction following discontinuation of use, right?

A. Correct.

Q. And armed with this article, you did nothing?

MR. MORROW: Objection.

THE WITNESS: Correct.

BY MR. BECKER:

Q. Let me show you --

- - -

(Whereupon, Exhibit-56, Irwig Article, "Persistent Sexual Side Effects of Finasteride for Male Pattern Hair Loss," Bates MRKP0002137734-40, was marked for identification.)

- - -

MR. BECKER: Sorry, guys, I only have two of these. No, I have three.

56.

MR. MORROW: Give me a minute.

MR. BECKER: Take your time.

So I've got two or three more documents before a natural

stopping point. Do you want to press forward to, like, 12:30-ish? It's up to all you. You're the witness and you guys --

MR. MORROW: I'm sorry, say it again.

MR. BECKER: I have, like, two or three more documents until a natural break. We'll go to about 12:30? But you have a witness and you guys are the court reporter. So whatever you want to do.

MR. MORROW: How do you feel? Do you want to keep going or do you want to take a break?

MR. BECKER: The faster we go, the faster we end.

THE WITNESS: Let's see what it looks like.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

BY MR. BECKER:

Q. So I have in front of you there, Doctor, Exhibit-56.

Do you see that there?

A. Yes.

Q. Okay. This also appeared in your custodial file.

Do you recall reviewing this document or reading this article?

A. I recall the article.

Q. Okay. It's an article from Dr. Irwig, of the George Washington University, entitled, "Persistent Sexual Side Effects for Finasteride For Male Pattern Hair Loss."

Did I read that correctly?

A. Yes.

Q. And it appears in the Journal of Sexual -- Sex Medicine, correct?

MR. MORROW: Objection.

THE WITNESS: Yes.

BY MR. BECKER:

Q. The article is dated 2011.

Do you see that there?

A. Yes.

Q. I want to go through just some of his results.

All right. You recall reading this article at the time you received it?

A. I read it at the time I received it, yes.

Q. And in connection with that, you had an understanding that Dr. Irwig had evaluated a cohort of men who believed that they had persistent ongoing sexual dysfunction following discontinuation of use, correct?

A. Yes.

Q. And he reported, after that review, that 94 percent of the subjects developed low libido, correct?

MR. MORROW: Objection.

THE WITNESS: That's what the statement says here.

BY MR. BECKER:

Q. And 92 percent developed

erectile dysfunction.

Do you see that?

A. Yes.

MR. MORROW: Form.

BY MR. BECKER:

Q. 92 developed decreased arousal?

MR. MORROW: Object to the form.

THE WITNESS: Yes.

BY MR. BECKER:

Q. And 69 percent developed problems with orgasms.

Do you see that there?

MR. MORROW: Object to the form.

THE WITNESS: Yes.

BY MR. BECKER:

Q. Do you have any evidence, as you sit here today, that that data was, in fact, inaccurate?

MR. MORROW: Objection.

This is.

THE WITNESS: This is a

selected group of patients with sexual AEs following finasteride.

BY MR. BECKER:

Q. Right. I mean, it's men who are saying, I continue to have adverse events -- I continue to have sexual dysfunction following the time I stopped taking PROPECIA®, right?

A. Yes.

MR. MORROW: Objection.

BY MR. BECKER:

Q. And they're reporting these are their symptoms, true?

A. Yes.

Q. What, if anything, did Merck do with this data?

MR. MORROW: Object to the form.

THE WITNESS: We reviewed the paper.

BY MR. BECKER:

Q. And based upon your review, what did you do?

A. I don't recall that we took

any action, if that's what you're asking.

Q. He reports that, The mean duration of finasteride use was 28 months and the mean duration of persistent sexual side effects was 40 months from the time of finasteride cessation to the interview date.

Do you see that?

A. I do.

Q. Would 40 months constitute persistent ongoing sexual dysfunction?

MR. MORROW: Objection.

THE WITNESS: I don't have a definition for persistent.

BY MR. BECKER:

Q. So if a label talks about symptoms being resolved upon discontinuation of use, don't you think it would be fair to tell doctors and patients what the temporal nexus was between the time the person discontinued the use and the date when the symptoms actually went away?

MR. MORROW: Objection.

THE WITNESS: Well, we didn't. We stated they were resolved upon discontinuation.

BY MR. BECKER:

Q. But let's assume for argument's sake that these men's symptoms resolved at 40 months. Isn't there a difference between a label that says your symptoms will resolve 40 months after you discontinue use versus your symptoms will ultimately resolve?

Isn't there a fundamental difference between those two statements?

MR. MORROW: Object to the form.

THE WITNESS: There is a difference.

BY MR. BECKER:

Q. Is Merck putting patient safety first when it refuses to identify the temporal connection between discontinuation of drugs and how long it takes for those symptoms to actually resolve?

MR. MORROW: Object to the form.

THE WITNESS: No. The persistence of sexual AEs has been added to the label based on postmarketing. We've also established that postmarketing data is limited. And this author himself cites the limitations of this study; the post hoc approach, selection bias, record bias, no serum hormone level.

MR. BECKER: Objection, nonresponsive. Move to strike everything after "no."

MR. MORROW: Objection.

BY MR. BECKER:

Q. My question is, Doctor, if we can agree that time from discontinuation to resolution is important, shouldn't you tell patients what that time is?

MR. MORROW: Object to the form. That's a different

question.

THE WITNESS: It would appear to be very variable for each of these patients.

BY MR. BECKER:

Q. That didn't answer my question.

You either should or shouldn't have to tell them what the time is.

What's your view?

MR. MORROW: Objection.

THE WITNESS: I don't think there's a need to tell them the time.

BY MR. BECKER:

Q. So in Merck's view, if the time to resolution was three and-a-half years, it would be okay to withhold that information from patients?

MR. MORROW: Object to the form. Mischaracterizes the testimony.

You may answer.

THE WITNESS: No, that shouldn't be withheld from the patient.

BY MR. BECKER:

Q. So at what point in time does persistence become -- at what point in time do you believe Merck should alert patients that it takes to resolve these symptoms after discontinuation?

MR. MORROW: Object to the form.

MR. BECKER: Let me start over because I agree with his objection on that one.

BY MR. BECKER:

Q. It's fair there's no -- there's no indication in the label that symptoms will resolve after a given amount of time has passed, right?

A. Right.

Q. All the label says is that stop taking the drug and the symptoms go away?

A. Uh-huh.

Q. Yes?
A. Yes. In the clinical trials --
MR. MORROW: Objection.
THE WITNESS: -- yes.
BY MR. BECKER:
Q. Isn't it a fair inference from that, that the symptoms resolve quickly after you discontinue use?
MR. MORROW: Objection. Speculation.
THE WITNESS: Based on the clinical trials, I don't believe it was a long time.
BY MR. BECKER:
Q. That wasn't my question.
My question was, wasn't the inference that Merck was making was that symptoms would quickly resolve upon discontinuation of use?
MR. MORROW: Object to the form.
THE WITNESS: I don't know that the argument was quickly

resolve. We just said that they would -- they resolved on discontinuation, what we saw in the clinical trials.

BY MR. BECKER:

Q. Can we -- would you agree with me that the longer it takes to have these symptoms resolve after discontinuation of use, the more obligation Merck has to alert patients of that -- of that issue?

MR. MORROW: Object to the form.

THE WITNESS: We now have reports in the adverse experiences section that talk about persistence. We don't put a qualifying -- a qualifying time period on that.

MR. BECKER: Objection. Hold on. Nonresponsive. Move to strike.

BY MR. BECKER:

Q. Let me see if I can do it

this way, Doctor.

Would you agree that if in some men these symptoms occurred six months after discontinuation of use, that Merck would have an obligation to report that in the label?

MR. MORROW: Objection.

THE WITNESS: Do you mean that these events had a new onset six months after?

BY MR. BECKER:

Q. No, no. I'm asking you, Merck does not dispute the fact that sexual -- adverse sexual events can occur while on a drug; you don't dispute that, do you?

A. No.

Q. Merck takes the position that at some point following discontinuation of use, those symptoms go away, right?

A. As observed in the trials, yes.

Q. What I'm trying to get at

is, how long after discontinuation of use should Merck tell patients and doctors those symptoms take to resolve?

Do you understand my question?

A. I do understand the question.

MR. MORROW: Objection.

You can answer.

BY MR. BECKER:

Q. And my question is, would you agree that if the symptoms did not resolve for a month, that Merck should alert patients who take the drug that it may take up to a month for their sexual dysfunction -- for their sexual function to return?

MR. MORROW: Objection.

BY MR. BECKER:

Q. Should you tell patients that?

MR. MORROW: Objection.

BY MR. BECKER:

Q. Should you tell patients

that?

MR. MORROW: Objection.

THE WITNESS: If we had that information, yes.

BY MR. BECKER:

Q. Okay. Now, you have a worldwide adverse event database, right?

A. Yes.

Q. And you had clinical trials, right?

A. Yes.

Q. And in those clinical trials, the data reported resolution after discontinuation of use for some patients, right?

A. Yes, yes.

Q. And sometimes that resolution took several hundred days or up to a year, right?

MR. MORROW: Objection.

THE WITNESS: I don't know that.

BY MR. BECKER:

Q. If the data demonstrates

that resolution took a long time following discontinuation of use, shouldn't you have told patients and doctors that?

MR. MORROW: Object to the form.

THE WITNESS: I don't remember the data on how long it took to -- for resolution.

BY MR. BECKER:

Q. That wasn't my question, though.

A. I understand.

Q. So I'd like an answer to my question.

MR. MORROW: Same objection.

THE WITNESS: If -- it may have been useful to put that in.

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(Whereupon, Exhibit-57, 4/6/11 E-mail to Cynthia Silber from Christine Alberts, Bates MRKP0001390080-81, was marked for identification.)

was drawing a distinction between Europe and the U.S., so I was trying to talk to you about that.

So let me see if I can do it this way.

MR. MORROW: Objection.

BY MR. BECKER:

Q. Why did you conduct this review in April of 2011?

A. I don't recall.

Q. Do you think it might have been in response to the mounting evidence from the Traish article, the Irwig article and Merck's own experience with sale and distribution of the drug?

MR. MORROW: Object to the form.

THE WITNESS: I don't recall.

BY MR. BECKER:

Q. Okay. Now, if you look at Exhibit 58 --

A. Yes.

Q. -- it says, in Paragraph 2,

To identify cases that may represent persistent sexual dysfunction, the MAH reviewed the reports with an outcome of not recovered in whom finasteride therapy was discontinued.

Do you see that there?

A. Yes.

Q. And it found a total of 446 reports, right?

A. Yes.

Q. You then went back and looked at the Worldwide Adverse Experience System, right?

MR. MORROW: Objection.

BY MR. BECKER:

Q. Or that was in context with the Worldwide Adverse Experience System, true?

A. Yes.

MR. MORROW: Objection.

THE WITNESS: Yes.

BY MR. BECKER:

Q. And this memo indicates, The Worldwide Adverse Experience System, WAES

database, was searched for spontaneous reports of sexual dysfunction received from healthcare providers, including regulatory agencies and consumers and patients on therapy with finasteride, 1 milligram, and .2 milligram tablet PROPECIA®, from market introduction, 11 September 1998, to 31 December 2010.

Do you see that?

A. Yes.

Q. Did I read that correctly?

A. Yes.

Q. And then it goes on to identify the search terms, right?

A. Yes.

Q. Persistence is not included in this search term, is it?

A. There is no term for persistence.

Q. That was my next question.

The reason why it's not included is because you didn't have a field in the MedDRA database to chronicle persistence, right?

MR. MORROW: Object to the form.

THE WITNESS: It's not that we don't have a field, MedDRA doesn't have the field.

BY MR. BECKER:

Q. You could have created one, right?

MR. MORROW: Objection.

THE WITNESS: I'm not sure of the process for creating terms.

BY MR. BECKER:

Q. Are you saying that you were absolutely precluded from looking or -- at a term that existed within the narrative reports of the adverse event database?

MR. MORROW: Objection.

THE WITNESS: I'm not saying we were precluded. I think the next paragraph explains what -- what the CREMS group did to uncover adverse experiences that were continuing after the

discontinued -- not recovered after they discontinued the drug. That's how they did it.

BY MR. BECKER:

Q. Doctor, I really need you to answer the questions I'm asking.

MR. MORROW: She is answering the questions.

MR. BECKER: She is not answering. She is not.

MR. MORROW: You just don't like it.

MR. BECKER: Believe me, there's plenty in this depo I like.

MR. MORROW: Move to strike.

BY MR. BECKER:

Q. There -- there was no term for persistence in the MedDRA database, right?

MR. MORROW: Objection.

THE WITNESS: There was no term.

BY MR. BECKER:

Q. There was no term for withdrawal syndrome in the MedDRA database, right?
A. I don't know that.
Q. There was no term for not recovered in the MedDRA database, right?
A. I don't know that.
MR. MORROW: Objection.
BY MR. BECKER:
Q. The term you searched was not recovered, right?
MR. MORROW: Objection.
THE WITNESS: We searched for an outcome of not recovered on the adverse experience reports.
BY MR. BECKER:
Q. So the only way that you could do that was if you actually found all of the reports and read all of the narratives, right?
MR. MORROW: Object to the form.
THE WITNESS: I'm not sure about that.

BY MR. BECKER:

Q. You don't have any -- with these other terms, you can run a query within MedDRA to actually pull up these various adverse events, right?

A. All these adverse experience terms, yes.

Q. Wouldn't it have been easier, from a postmarketing surveillance standpoint, to actually include a term for persistence?

MR. MORROW: Object to the form.

THE WITNESS: I don't know whether it would have been easier.

BY MR. BECKER:

Q. But you knew that persistence might be a problem as early as 1998, right?

MR. MORROW: Objection.

THE WITNESS: We knew -- 1998?

BY MR. BECKER:

Q. Dr. Kaufman wrote about

ejaculate disorders in 1998, that reversibility was impossible -- reversibility upon discontinuation was impossible, due to postmarketing reports, right? You remember that document?

MR. MORROW: Objection.

THE WITNESS: It was impossible to establish based on postmarketing reports.

BY MR. BECKER:

Q. So you knew as early as 1998 that some men were continuing to experience sexual dysfunction following discontinuation of use, right?

MR. MORROW: Object to the form. Mischaracterizes prior testimony.

You may answer.

THE WITNESS: Could you repeat that question?

BY MR. BECKER:

Q. Based on Dr. Kaufman's e-mail, Merck was aware of the fact, as early as 1998, that there were reports of

persistent ongoing sexual dysfunction following discontinuation of use, true?

MR. MORROW: Same objection.

THE WITNESS: I understood Dr. Kaufman's e-mail to mean that you couldn't prove reversibility from postmarketing reports, not --

BY MR. BECKER:

Q. Let's go to something you do understand.

MR. MORROW: Are you finished with your answer?

BY MR. BECKER:

Q. Were you finished with your answer?

A. Yes.

Q. You received an e-mail in 2000 that provided evidence of persistent ongoing sexual dysfunction from the clinical trial itself, right?

MR. MORROW: Objection.

THE WITNESS: We reviewed that e-mail. We had an e-mail, with no data on it, that said that

A. No.

MR. MORROW: Objection.

BY MR. BECKER:

Q. The drug is on the market with a label that talks about persistence?

A. It has a label, adverse events in the postmarketing --

Q. So a doctor reading that --

A. -- section. It does not contain that in the warning section of the label.

Q. A doctor reading that would be able to counsel his or her patient on reports of ongoing persistent erectile dysfunction so as the patient could make an informed choice, right?

MR. MORROW: Object to the form.

THE WITNESS: Yes.

BY MR. BECKER:

Q. That wasn't in the label prior to 2012 in the United States, right?

A. No.

MR. MORROW: Objection.

BY MR. BECKER:

Q. So prior to 2012, when that finally made it into the label, does the benefit of hair growth outweigh the risk of persistent to permanent erectile dysfunction?

MR. MORROW: Object to the form.

THE WITNESS: That has to be a choice for the patient seeking treatment.

BY MR. BECKER:

Q. How does a patient make an informed choice if they don't know the risk is present?

A. They can't.

MR. MORROW: Object to the form.

BY MR. BECKER:

Q. Exactly. And so prior to 2012 when the FDA approved the label, the only person or people that could make

that assessment was Merck, right?

MR. MORROW: Objection.

THE WITNESS: Based on the label in the U.S., the physician did not have that information.

BY MR. BECKER:

Q. Right. So the only people that had that information at their disposal were, in fact, Merck, right?

MR. MORROW: Objection.

THE WITNESS: It was in the EU label.

BY MR. BECKER:

Q. Right. But you testified earlier, you have no idea if you gave this document to the FDA, right?

MR. MORROW: Objection.

THE WITNESS: I did.

BY MR. BECKER:

Q. And so if the FDA didn't have this data, there would be no way they could evaluate it, right?

MR. MORROW: Objection.

THE WITNESS: The FDA -- I'm